UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,665	12/05/2003	Satyanarayana Medicherla	219002032800	1249

25225 7590 10/23/2006

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
ZHANG, NANCY L	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,665	MEDICHERLA ET AL.	
	Examiner	Art Unit	
	Nancy L. Zhang	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 sheets*. 4/19/04, 9/17/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-5), a method of preventing Type I diabetes by administering a pharmaceutically effective amount of a p38 MAPK inhibitor, in the reply filed on 4/27/2006 is acknowledged. The traversal is on the ground that all claims fall within the same classification of 514. This is not found persuasive because the patient population in the method of Group II is different from the patient population in the method of Group I and Group III. Therefore, the methods of Group I, II and III are distinct.

The requirement is still deemed proper and is therefore made FINAL.

Due to applicant's amendment made in claims 6 and 9, claims 6 and 9 are now directed to the elected invention of Group I. Accordingly, claims 6 and 9 are examined together with the invention of Group I.

Claims 1-6 and 9 are examined.

Information Disclosure Statement

The information disclosure statement filed on 09/17/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because reference under "OTHER DOCUMENTS" cites an International Search Report. An International Search Report is not a published document.

The information disclosure statement filed 4/19/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the publications listed under

"OTHER DOCUMENTS" do not identify the titles of the publications except for items 38 and 48. In addition, the relevant pages for item 38 are not identified.

It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "to prevent" (line 4) renders the claim indefinite because it is unclear whether the claimed invention is a method of treatment or a method of prevention. See MPEP § 2173.05(d).

Appropriate correction is required.

Scope of enablement Rejection - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating type 1 diabetes with p38 MAP kinase inhibitors, does not reasonably provide enablement for preventing type 1 diabetes with p38 MAP kinase inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-6 and 9 recite a method of treating type 1 diabetes comprising administering a pharmaceutically effective amount of a p38 MAP kinase inhibitor sufficient to prevent onset of type 1 diabetes.

The ability of preventing type I diabetes is not yet known in the art. Billespie (see abstract only, "Type 1 diabetes: pathogenesis and prevention", CMAJ, 2006 Jul 18; 175(2): 165-170) discusses potential attainable target for preventive strategies for Type 1 diabetes and the fact that no current "cure" exists. The burden of enabling one skilled in the art to prevent type I diabetes would be much greater than that of enabling treatment of such disease. The specification has not provided evidence or convincing mechanistic reasoning that diabetes can be prevented by the administration of p38 MAP kinase inhibitors.

The specification of the instant application does not provide guidance as to how one skilled in the art would accomplish the objective of preventing type 1 diabetes. Nor is there any guidance provided as to the amount of p38 MAP kinase inhibitors or how to determine the amount of p38 MAP kinase inhibitors sufficient to prevent type I diabetes.

Therefore, based on the unpredictable nature of the invention and state of the prior art, the lack of guidance and the breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mavunkel et al. (US Patent 6,589,954, filing date: May 21, 1999) in view of Faustman (PGPub US 2002/0123472, pub. date: Sep. 5, 2002).

Claims 1-6 and 9 recite a method of treating Type I diabetes comprising administering a pharmaceutically effective amount of a p38 MAP kinase inhibitor.

Mavunkel et al. disclose compounds of p38 MAP kinase inhibitors useful in treating conditions associated with inflammation (column 17, lines 23-24) and that the compounds are used for the treatment of mammals including human (column 17, lines 26-28). The compounds disclosed by Mavunkel et al. inhibit a member of the MAP kinase family variously called p38 MAPK (column 17, lines 37-39). Mavunkel et al. further disclose that the compounds selectively inhibit the activity of the p38α isoform (column 18, lines 63-64) and the compounds are useful for treating conditions associated with activation of p38α.

Mavunkel et al. do not teach the treatment of Type 1 diabetes using the compounds of p38 MAPK inhibitors. However, Faustman discloses that Type 1 diabetes is caused by an autoimmune reaction (page 1, paragraph [0002], lines 9-10) and many of the major approved therapies for such autoimmune diseases (type 1 diabetes) involve the administration of anti-inflammatory drugs that inhibit the production of TNF-alpha (page 2, left column, lines 1-3). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer the anti-inflammatory drug of p38 MAPK inhibitors as disclosed by Mavunkel et al. to treat type 1 diabetes. The motivation to do so is provided by Faustman that many major

approved therapies for type 1 diabetes involve the administration of anti-inflammatory drugs that inhibit the production of TNF (Faustman, page 2, left column, lines 1-3) and by Mavunkel et al. that the compounds of p38 MAPK inhibitors are useful in treating conditions associated with inflammation (column 17, lines 23-24) and they inhibit the production of TNF cytokines (Mavunkel, column 17, lines 33-34).

Therefore, the invention as claimed in claims 1-6 and 9 was prima facie obvious over the combined teachings of Mavunkel et al. and Faustman.

The recitation in claims 2, 3, 6 and 9 regarding the results of treatment in the subject by administering p38 MAPK inhibitor do not limit the method because there is no additional step in the method to test the results of treatment. Thus this recitation is viewed as a scientific explanation and/or property of the method of treatment.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the

applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Revesz (US Patent 6,300,347, issue date: Oct. 9, 2001).

Claims 1-3, 5-6 and 9 recite a method of treating type 1 diabetes comprising administering a pharmaceutically effective amount of a p38 MAP kinase inhibitor.

Revesz discloses compounds having p38 MAP inhibiting activity (see abstract) that are particularly useful for the treatment of conditions such as type 1 diabetes (column 20, line 43). Revesz further discloses that the subject of treatment can be a human (column 21, line 37).

Therefore, a method of treating type 1 diabetes in human by administering a p38 MAP kinase inhibitor is clearly anticipated.

The recitation in claims 2, 3, 6 and 9 regarding the results of treatment in the subject by administering p38 MAPK inhibitor do not limit the method because there is no

additional step in the method to test the results of treatment. Thus this recitation is viewed as a scientific explanation and/or property of the method of treatment.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

nlz 10/11/06

NLZ

Ardin H. Marschel 10/14/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER